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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,894	08/04/2003	Scott Powers	018781-004721US	5609

7590 09/15/2005

BANNER & WITCOFF
1001 G STREET, N.W.
WASHINGTON, DC 20001

EXAMINER

ULM, JOHN D

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 09/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/633,894

Applicant(s)

POWERS ET AL.

Examiner

John D. Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42,44,45 and 47-49 is/are rejected.
- 7) ☒ Claim(s) 43,46,50 and 51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

1) Claims 42 to 51 are pending in the instant application. Claims 42 to 46 have been amended and claims 47 to 51 have been added as requested by Applicant in the correspondence filed 06 July of 2005.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 42, 44 and 45 are 42, 44, 45 and 47 to 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Nef et al. publication (P.N.A.S. 89:8948-8952, Oct. 1992) essentially for those reasons of record as applied to claims 42, 44 and 45 in section 3 of the previous office action. As stated therein these claims encompass a polyclonal antibody that "specifically binds to the polypeptide of SEQ ID NO:6", and an Fv fragment thereof. The instant claims encompass polyclonal antisera raised against any protein that shares at least one epitope with SEQ ID NO:2. The protein described as mouse OR3 in Figure 1 of the Nef et al. publication shares a plurality of epitopes with SEQ ID NO:2 of the instant application, including the sequences LHTPMYFFL, KTISYGGCV, WLGATEC, CRPLHY, SWLGGL, DTSLNE, EGRRKAFNTC, and NPLIYTLRN. Because the production of polyclonal antibodies to a particular protein for the purposes of purification and *in situ* visualization of that protein were old and well known in the art at the time of the instant invention, as conceded by the text on pages 21 and 22 of the instant application, an artisan would have found it *prima facie* obvious to have produced polyclonal antibodies to the OR3 receptor protein of Nef et al. by

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employing those methods that were routine in the art at that time to facilitate the purification, characterization, and *in situ* visualization of that protein, at the time that the instant application was filed. Because OR3 shares a plurality of epitopes with SEQ ID NO:2, the instant claims encompass polyclonal antisera the has been raised against OR3.

This rejection is based upon two premises. The first is that the production of polyclonal antisera to a known protein was a practice that was old and well known in the art of receptor biology at the time that the instant invention was made. Second, polyclonal antisera to the OR3 protein of Nef et al. will cross react with a polypeptide consisting of the amino acid sequence presented in SEQ ID NO:6 of the instant application and, therefore, such antisera is encompassed by the instant claims. Applicant has failed to identify any error in the premises upon which the instant rejection is based.

Applicant has traversed this rejection on the basis that Nef et al. does not disclose antibodies to OR3. Clearly, had Nef et al. disclosed such antibodies then that reference would have been anticipatory. The instant rejection is based upon obviousness. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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In the instant case, the only difference between Nef et al. and the instant claims is that Nef et al. did not describe antibodies to OR3. The text on pages 21 and 22 of the instant specification shows that the production of polyclonal antibodies to a particular protein for the purposes of purification and *in situ* visualization of that protein were old and well known in the art at the time of the instant invention which constitutes objective evidence present in the application indicating obviousness of producing antibodies to a known protein. Therefore, the production of polyclonal antisera to the OR3 protein of Nef et al. was *prima facie* obvious to one of ordinary skill in the art of receptor biology in view of this reference in conjunction with those routine practices that were well known in the art at the time of the Nef et al. publication.

Applicant's argument that the definition of the limitation "specifically binds" provided on page 22 of the specification excludes cross-reactive antibodies is not persuasive because that definition is vague and ambiguous. For example, the statement "'specifically (or selectively) binds" to an antibody or "specifically (or selectively) immunoreactive with," when referring to a protein or peptide, refers to a binding reaction that is determinative of the presence of the protein in a heterogeneous population of proteins and other biologics" is ambiguous because the composition of the "heterogeneous population of proteins and other biologics" is critical to the determination of whether a particular antibody meets this limitation and the composition of this reference material is not provided. For example, if the "heterogeneous population of proteins and other biologics" is composed exclusively of human proteins or, more precisely, human blood proteins, then polyclonal antisera to OR3 would be

expected to only bind to a protein of SEQ NO:6. Such antibodies would, therefore, meet the "specifically binds" limitation of the instant claims. The limitation "specifically binds" clearly encompasses antibodies that bind to proteins other than SEQ ID NO:6 because Applicant's definition states that "polyclonal antibodies raised to a particular BCA-GPCR can be selected to obtain only those polyclonal antibodies that are specifically immunoreactive with the BCA-GPCR, and not with other proteins, except for polymorphic variants, orthologs, and alleles of the BCA-GPCR". The ambiguity of Applicant's definition is further illustrated by the statement that "this selection may be achieved by subtracting out antibodies that cross-react with BCA-GPCR molecules". The term "cross-react" requires at least two points of reference and only one is given. Because the definition of the limitation "specifically binds" that is provided by the instant specification is ambiguous then this limitation must be given its broadest reasonable interpretation in light of that definition, and that is the interpretation employed in the original rejection. Because the specification makes it impossible to identify that subject matter which is excluded by this limitation, then the claims are being examined in accordance with what subject matter is certain to be included by that limitation, and that includes antibodies to any protein sharing one or more epitopes with SEQ ID NO:6.

5) Claims 43, 46, 50 and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6) Applicant's arguments filed 06 July of 2005 have been fully considered but they are not persuasive.

7) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

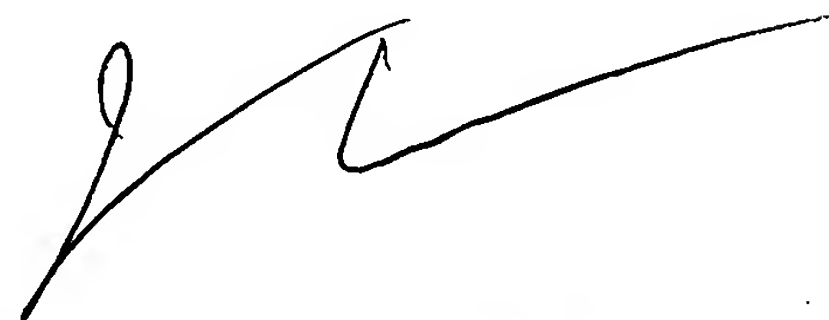
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN ULM
PRIMARY EXAMINER
GROUP 1800